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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/900,575 | 07/06/2001 | Solomon Langermann | 469201-549 | 4081 |

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01/02/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/02/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,575

Applicant(s)

LANGERMANN ET AL.

Examiner

Padmavathi v Baskar

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 and 11-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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DETAILED ACTION

1. Applicant's amendment filed on 11/13/02 is acknowledged. Claims 1-38 are pending in the application.

Priority

2. Applicant's claim the benefit of U.S. Provisional Application NO: 60/216,750 filed on 7/7/2000 under 35 U.S.C. 119(e) for domestic priority is acknowledged.

Drawings

3. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details.

Information Disclosure Statement

4. No Information Disclosure Statement filed with this application.

Election

5. Applicant's election of Group I claims 1-6 and 10-12 with respect to SEQ.ID.NO: 29 drawn to polypeptide in Paper # 7, 11/13/02 with traverse is acknowledged. Claims 7-9 and 13-38 are withdrawn from consideration as the claims are drawn to non-elected invention. Claims 4-6 and 11-12 are also withdrawn since these claims are not drawn to the elected invention, i.e., SEQ.ID.NO: 29. Claims 1-3 and 10 with respect to SEQ.ID.NO: 29 are under examination. Applicant is advised to limit the invention to SEQ.ID.NO: 29.

Applicant requests the Examiner to reconsider the restriction and withdraw the restriction requirement and examine the claims related to method of use of the elected product. The traversal is on the ground(s) that the search and examination of one group would disclose the other. This is not found persuasive because the claims are distinct and independent and acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The inventions of the groups are drawn to different compositions and

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therefore, are patentably distinct because they have materially different physical and chemical properties, structures, and utilities. The structure, function and utilities of various polypeptides will be different. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group, would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues (for example enablement) also exist.

It is noted that the restriction of one SEQ.ID.NO is not an election of species. The examiner made it clear on the record in paper # 6 (9/12//02) paragraph 3 that the disclosed sequences are considered as patentably distinct and different inventions since each SEQ.ID.NO is distinct and given a specific sequence identification number i.e., SEQ.ID.NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12-38 containing different amino acids. Burden in examining materially different polypeptides having materially different issues also exist. Restriction is deemed proper because these products appear to constitute patentably distinct inventions and is therefore made FINAL.

Claim Rejections - 35 USC 112, second paragraph.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 2-3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 is vague and indefinite for the recitation of "further comprising about the N-terminal two third of the sequence selected from SEQ.ID.NO: 29." Does this polypeptide contain amino acids 26-186 of SEQ.ID.NO: 29 + two thirds of N-terminal sequence of SEQ.ID.NO: 29? As written the claim is confusing and difficult to understand the metes and bound of comprising about the N-terminal two third of the sequence selected from SEQ.ID.NO: 29 since this sequence contains 279 amino acids.

Claim 3 is vague in reciting "an amino acid sequence". It is not clear whether the immunogenic polypeptide comprises less than an amino acid sequence of polypeptide SEQ.ID.NO: 29 since the claims recite "an amino acid sequence".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number: AC P08191 or Krogfelt et al (Infect Immun 1990 Jun; 58(6): 1995-8).

Claims are drawn to an immunogenic composition and a vaccine composition comprising a sequence selected from residues 26-186 of SEQ.ID.NO: 29, N-terminal sequence and an amino acid sequence SEQ.ID.NO: 29 and a pharmaceutical carrier.

The prior art Accession number AC P08191 discloses an immunogenic composition and a vaccine composition comprising a sequence selected from 26-1⁸⁶19 residues of SEQ.ID.NO: 29 (see the enclosed alignment). The prior art anticipated the claimed invention.

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Or

Krogfelt et al disclosed FimH protein (figure 2, lane B1 and abstract) attached to a carrier protein in buffer (pharmaceutically acceptable carrier) from fimbriae of Escherichia coli. In the absence of evidence to the contrary the disclosed prior art FimH protein comprises a sequence selected from residues 26-186 of SEQ.ID.NO: 29. The prior art anticipated the claimed invention.

It is acknowledged that under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same polypeptide and formulations thereof as claimed. Therefore AC P08191 or Krogfelt et al meet the vaccine composition limitation of the claim 10.

In re Thorpe, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Conclusions

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

12/8/02